RPE funds prior to February 28, 2002. Award Date: January 1, 2002.

Cycle B: April 1, 2002. For all other States and Territories. Award Date: June 1, 2002.

G. Human Subjects

a. The applicant should describe the degree to which human subjects may be at risk and what protections will be in place to assure protection and confidentiality.

b. The applicant should demonstrate that it has adequately addressed the requirements of Title 45 CFR Part 46 for the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

1. a progress report shall be submitted annually, no later than 90 days after the end of each budget period.

2. a financial status report shall be submitted, no later than 90 days after the end of each budget period.

3. a final financial status report shall be submitted, no later than 90 days after the end of the five year project period.

The following additional requirements are applicable to this program. For a complete description of each see Addendum 1.

AR–1 Human Subjects Requirements
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

In addition to being authorized under 301 (a) (42 U.S.C. 241(a)) of the Public Health Service Act, this program announcement is also authorized under 391 (a) and 393B (42 U.S.C. 280(b) et seq) of the Public Health Service Act. The catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC homepage on the Internet http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:Sheryl Heard, Grants Management Specialist,Grants Management Branch,Procurement and Grants Office,Program Announcement 02002,Centers for Disease Control and Prevention (CDC) 2920 Brandywine Road, Room 3000 Atlanta, Georgia 30341 Telephone: (770) 488–2723 Email address: slh3@cdc.gov

For program technical assistance, contact:Wendy Watkins, Program Manager,Division of Violence Prevention,National Center for Injury Prevention and Control,Centers for Disease Control and Prevention (CDC) 4770 Buford Highway, NE, Mailstop K–58 Atlanta, GA 30341–3724 Telephone: (770) 488–1567 Email address: dmw7@cdc.gov.

Dated: August 13, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–20753 Filed 8–16–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0174]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; FDA Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 17, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Recall Regulations—Part 7 (21 CFR Part 7 (Subpart C))—(OMB Control Number 0910–0249)—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7, subpart C sets forth the recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA-regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluating return reply cards, effectiveness checks, and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2000. The resulting number of recalls from this database search (1,933) is used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the above information to be 157,675 burden hours.

In the **Federal Register** of May 1, 2001 (66 FR 21767), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received on the information collection.

We agree with the comment that the agency is slow in providing the recall classification letter to recalling firms and are taking steps to streamline the classification process which, in turn, will improve the timeliness of the classification letter. However, we

believe that recalling firms are usually aware of the significance of the defect in a recalled product and know the likely FDA classification. This may be based on the firm's own health hazard evaluation, by precedent recalls and information published on FDA's Web sites, and/or by verbal communication with FDA district office recall coordinators. The latter is especially true regarding the classification of serious to potentially life-threatening hazard-to-health recall actions (class I). In such situations, the delivery of a classification letter usually follows extensive communications between recalling firms and FDA in which classification, recall strategy, and press releases are immediately discussed.

We have accepted the commenter's estimate of the time expended to conduct recalls and have used those figures, coupled with revised recall numbers, to develop what we believe to be a more realistic estimate of the time expended by FDA-regulated industry to develop and report recall information requested by FDA.

FDA agrees with the comment to have a process whereby reports and any other necessary information can be submitted by e-mail. In many cases, this has become routine for some firms and FDA district offices. Certainly there is no reason not to use e-mail or facsimile communications in most recall situations; however, FDA would maintain the prerogative for investigational visits and other in-person communications where the agency considers it appropriate. In fact, FDA is currently working toward providing ''industry guidance'' online which will provide a format for industry responses to recall situations.

At the present time, the names and telephone numbers of FDA's district office recall coordinators may be found on the Internet at http://www.fda.gov/ora/inspect—ref/iom/iomoradir—monitors.html#RECALL. Unfortunately, this provides information from FDA's latest published location directory and is not always current. We will see that this list is updated if it is possible to do so. Additionally, changes to the FDA Web site's recall information and reporting systems which are currently under development, will maintain an easy to locate, user-friendly recall section that will include a current listing of all district coordinators that will include names, telephone and facsimile numbers, mail, and e-mail addresses.

At this time, we will refer to the Center for Food Safety and Applied Nutrition your suggestion to allow processing authorities to authorize reconditioning/destruction of thermally processed low acid and acidified foods in hermetically sealed containers and for the recalling firm to then submit a summary of the disposition action to FDA.

As a result of the comment received, the following is a revised summary of the estimated annual burden hours for manufacturers, processors, and distributors to comply with the voluntary reporting requirements of FDA's recall regulations.

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency perResponse	Total Annual Responses	Hours per Response	Total Hours
7.42	1,855	1	1,855	15	27,825
7.26 and 7.49	1,855	1	1,855	20	37,100
7.53	1,855	4	7,420	10	74,200
7.55(b)	1,855	1	1,855	10	18,550
Total					157,675

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 13, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20842 Filed 8–16–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 13, 2001, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations on the proposed approach for selection of delta in noninferiority (equivalence) clinical trials. The impact of this approach on studies of anti-infective drug products will be considered, with a focus on acute exacerbation of chronic bronchitis and hospital-acquired pneumonia.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 4, 2001. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and